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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,572	03/22/2001	Romulus Kimbro Brazzell	OP/4-31363A	4539

1095 7590 12/02/2004

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

EXAMINER

THOMPSON, KATHRYN L

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/814,572

Applicant(s)

BRAZZELL, ROMULUS KIMBRO

Examiner

Kathryn L. Thompson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-15, 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-15, 18, 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/27/2004.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 4, 7, 8, and 14 are rejected under 35 U.S.C. 102(a) as being anticipated by Dimitroff et al ("Anti-angiogenic activity of selected receptor tyrosine kinase inhibitors, PD166285 and PD173074: Implications for combination treatment with photodynamic therapy."). Dimitroff et al discloses a method for treating neovasculture in a subject comprising administering an effective amount of an anti-angiogenic agent to the subject, administering an effective amount of a photosensitive agent to the subject, and irradiating the neovasculture with light having a wavelength absorbable by the photosensitive agent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 9 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Brazzell et al ('819). Brazzell et al ('819) discloses wherein the anti-angiogenic agent is N-benzoyl-staurosporine.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark (US 6,297,228) in view of Dimitroff et al ("Anti-angiogenic activity of selected receptor tyrosine kinase inhibitors, PD166285 and PD173074: Implications for combination treatment with photodynamic therapy."). Clark discloses a method for treating neovasculature in a subject comprising administering an effective amount of an anti-angiogenic agent to the subject, administering an effective amount of a photosensitive agent to the subject, and irradiating the neovasculature with light having a wavelength absorbable by the photosensitive agent (Column 2, Lines 29-31), wherein the anti-angiogenic agent and the photosensitive agent are administered simultaneously (Column 6, Lines 5-8), wherein the subject is suffering from choroidal neovascularization, and wherein the subject is suffering from retinal neovascularization (Column 4, Lines 23-41). Clark does not disclose wherein the anti-angiogenic agent is selected from the group consisting of inhibitors of protein kinase C, antagonists of growth hormone, antagonists of IGF-1, antagonists of vascular endothelial growth factor, inhibitors of cyclooxygenase II, antagonists of angiotensin II, antagonists of NF-

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kappa B, and phospholipase A2 antagonists. Dimitroff et al does disclose wherein the anti-angiogenic agent is selected from the group consisting of inhibitors of protein kinase C, antagonists of growth hormone, antagonists of IGF-1, antagonists of vascular endothelial growth factor, inhibitors of cyclooxygenase II, antagonists of angiotensin II, antagonists of NF-kappa B, and phospholipase A2 antagonists. It would have been obvious to one with ordinary skill in the art to combine the teachings of Dimitroff et al and Clark to include a group consisting of inhibitors of protein kinase C, antagonists of growth hormone, antagonists of IGF-1, antagonists of vascular endothelial growth factor, inhibitors of cyclooxygenase II, antagonists of angiotensin II, antagonists of NF-kappa B, and phospholipase A2 antagonists since this group of anti-angiogenic agents is notoriously well known in the art.

Claims 2, 4, 5, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark in view of Dimitroff et al. Clark teaches all of the claimed limitations except administering the anti-angiogenic agent between about 0-4 weeks before administration of the photosensitive agent, administering the anti-angiogenic agent between about 0-4 weeks after administration of the photosensitive agent, and administering the anti-angiogenic agent between about 0-4 weeks before administration of the photosensitive agent and between about 0-4 weeks after administration of the photosensitive agent. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to choose between about 0 to about 4 weeks as the time interval because Applicant has not

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disclosed that using between about 0 to about 4 weeks as the time interval provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the time interval taught by Clark and Dimitroff et al or the claimed time interval because both time intervals perform the same function. Therefore, it would have been an obvious matter of design choice to modify Clark and Dimitroff et al to obtain the invention as specified in Claims 2, 4, and 5.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark in view Dimitroff et al, further in view of Richter et al (5,770,619). Clark and Dimitroff et al disclose all of the claimed limitations except wherein the photosensitive agent is selected from the group consisting of porphyrin and a purpurin, and a benzoporphyrin derivative monacid ring A. Richter et al discloses wherein the photosensitive agent is selected from the group consisting of porphyrin and a purpurin, and a benzoporphyrin derivative monacid ring A. It would have been obvious to one with ordinary skill in the art to use the teachings of Richter et al to modify the invention of Clark and Dimitroff et al wherein the photosensitive agent is selected from the group consisting of porphyrin and a purpurin, and a benzoporphyrin derivative monacid ring A since these are notoriously well known in the art as effective photosensitive agents.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dimitroff et al in view of Richter et al (US 5,770,619). Dimitroff et al disclose all of the claimed limitations except wherein the photosensitive agent is selected from the group consisting of porphyrin and a purpurin, and a benzoporphyrin derivative monacid

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ring A. Richter et al discloses wherein the photosensitive agent is selected from the group consisting of porphyrin and a purpurin, and a benzoporphyrin derivative monacid ring A. It would have been obvious to one with ordinary skill in the art to use the teachings of Richter et al to modify the invention of Dimitroff et al wherein the photosensitive agent is selected from the group consisting of porphyrin and a purpurin, and a benzoporphyrin derivative monacid ring A since these are notoriously well known in the art as effective photosensitive agents.

Response to Arguments

Applicant's arguments with respect to the Clark patent and claims 1-5, 7-15, 18, and 19 have been considered but are moot in view of the new ground(s) of rejection.

With regards to the Dimitroff et al article and claims 1, 4, 6, 7, 8, and 14, Applicant's arguments filed on August 4, 2004 have been fully considered but they are not persuasive. Applicant argues that Dimitroff et al fails to indicate ocular neovascularization. Examiner respectfully disagrees. Specifically, on page 122, second column, second paragraph, there is disclosure of experimental models of iris and retinal angiogenesis.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn L. Thompson whose telephone number is 703-305-3286. The examiner can normally be reached on 8:30 AM - 6:00 PM: 1st Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KLT



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